

Department of Health and Mental Hygiene

Lawrence J. Hogan, Jr., Governor - Boyd K. Rutherford, Lt. Governor -Van T. Mitchell, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299 Mitra Gavgani, Board President – Deena Speights-Napata, Executive Director

April 29, 2016

CERTIFIED & REGULAR MAIL RETURN RECEIPT REQUESTED CERTIFIED NUMBER: 7014 0510 0001 0446 7635

Care One Pharmacy 2277 Reisterstown Road Baltimore, Maryland 21217 Attn: Peter Okojie, R.Ph.

Re:

Permit No. P04122

Notice of Deficiencies, Recommended Civil Monetary Penalty, and

Opportunity for Hearing

Dear Mr. Okojie:

On January 28, 2016, the Board of Pharmacy (the "Board") conducted an annual inspection of Care One Pharmacy (the "Pharmacy") to ensure compliance of with federal and State laws governing the operation of a pharmacy. The Inspection Report indicated that the Pharmacy was not in compliance with regulatory requirements regarding registration of pharmacy staff. Specifically, a foreign-trained pharmacist was performing delegated pharmacy acts in the Pharmacy without a pharmacist intern or technician registration. The Board's records indicate that the subject individual subsequently obtain a pharmacy technician registration on March 3, 2016. The Board's records also indicate that the Pharmacy had a prior disciplinary action related to pharmacy staffing in January 2011.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated January 28, 2016, and attached as Exhibit A.

Based upon deficiencies cited at your Pharmacy, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. § 12-403(c)(1) and § 12-6B-01.

II. RECOMMENDED CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-410 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies cited at the Pharmacy, the Board hereby recommends the imposition of a **civil monetary penalty of \$2,500.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in this Notice.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

III. FOLLOW-UP INSPECTION

Please be advised that the Board of Pharmacy may perform a follow-up inspection of the Pharmacy to insure that the deficiencies noted herein have been addressed and corrected. Should the follow-up inspection indicate that the Pharmacy has further deficiencies, the Board may pursue further disciplinary action against the Pharmacy that may result in the imposition of sanctions such as suspension, revocation or additional monetary penalties.

IV. OPPORTUNITY FOR HEARING

If the Pharmacy disputes the findings, conclusions or the civil monetary penalty, the Pharmacy may request an evidentiary hearing on the Board's decision in this matter. In the event that the Pharmacy requests an evidentiary hearing, the Board shall initiate formal proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 et seq., and COMAR 10.34.01. Any request for a hearing must be submitted in writing to Heather McLaughlin, Compliance Coordinator, Maryland Board of Pharmacy, 4201 Patterson Ave., 1st Floor, Baltimore, Maryland 21215, no later than thirty (30) days of the date of this Notice.

Please be advised that at the hearing you would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on your own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Pharmacy guilty of the violations cited in the Reports, the Board may suspend or revoke the pharmacy permit, or impose civil penalties, or both. If you request a hearing but fail to appear, the Board may nevertheless hear and determine the matter in your absence.

V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY

Alternatively, the Pharmacy may pay the recommended civil monetary penalty within thirty (30) days of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy.

Please mail the check of money order to:

Maryland Board of Pharmacy P.O. Box 2051 Baltimore, MD 21203-2051

NOTE: Please include the case number, Pl-16-129, on your check or money order to insure proper assignment to your case.

Upon the Pharmacy's payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to the inspection report, dated January 28, 2016, and shall be a public document in accordance with the Maryland Public Information Act.

If you have any questions concerning the instructions contained in this letter, please contact Heather McLaughlin, Compliance Coordinator, at 410-764-4152.

Sincerely,

Deena Speights-Napata Executive Director

Linda Bethman, Board Counsel

CC:

Healthy People Healthy Communities

STATE OF MARYLAND

DHMH

P1-16-129

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

Maryland Board of Pharmacy

4201 Patterson Ave – Baltimore, MD – 21215-2299 Mitra Gavgani, President – LaVerne G. Naesea, Executive Director

Care One Pharmacy, LLC 2277 Reisterstown Road Baltimore, Maryland 21217 P04122

RE: Unlicensed Personnel

February 8, 2016

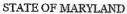
On January 28, 2016 I inspected Care One Pharmacy, LLC. During the inspection there was a Pharmacy Intern, Mahamoud Aljack on duty working on the computer filling and counting prescriptions. I checked the Board's website and Mr. Aljack was not found. Per Peter Okojie, Pharmacy Manager, Mr. Aljack had already sent his intern application to the Board and had not gotten a response. I requested a receipt of that transaction by 2/8/2015 nonetheless, it was never sent.

Sincerely,

Shanelle Young, Pharmacy Inspector

hancle young

pending does (intern)





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DHMH Department of Health and Mental Hygiene Laurence J. Hogan, Jr., Governor - Boyd K. Rutherford, Lt. Governor Van T. Nitchell, Secretary

MARYLAND BOARD OF PHARMACY 4201 Patterson Avenue • Baltimore, Maryland 21215-2299 Mitra Gavgani, Board President - LaVerne G. Naesea, Executive Director

COMMUNITY PHARMACY INSPECTION FORM

Corporate Pharmacy Name Care One Pharmacy, LLC
Pharmacy Name-Doing Business as (d/b/a) or Trade Name Care One Pharmacy
Street Address 2277 Reisterstown Road, Baltimore, Maryland 21217
Business Telephone Number 410-523-7500 Business Fax Number 410-523-7578 Inspection Date: 1/28/2016 Arrival Time: 9:30am Departure Time: 12pm
Type of Inspection: Annual Follow-up Previous Date: 3/10/2015 Arrival Time: 9:30am Departure Time: 12pm Previous Date: 3/10/2015
Name of Inspector: Shanelle Young
1. GENERAL INFORMATION
Yes No The pharmacy hours of operation are prominently displayed if the prescription area is not open the same hours as the establishment.
Pharmacy Hours M-F: 9am-6pm Sat: 10am-4pm Sun: Closed
Yes No All permits, licenses, and registrations are posted conspicuously. HO § 12-311, HO § 12-408(b) and HO § 12-6B-08
Maryland Pharmacy Permit Number P04122 Expiration Date: 5/31/2016
CDS Registration Number 458954 Expiration Date: 4/30/2016
DEA Registration Number BC9014616 Expiration Date: 8/31/2016
Yes No The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19
Yes No The pharmacy provides services to Comprehensive Care facilities or assisted living facilities. (If yes, complete Comprehensive Inspection Form) COMAR 10.34.23
Yes No The pharmacy fills original prescriptions received via the internet.
Yes No The pharmacy fills original prescriptions via e-prescribing.
Yes No The pharmacist fills mail order prescriptions.
If yes to any of the above, how does the pharmacist verify that a relationship exists between the patient and the prescriber? 21 C.F.R. § 1306.04, HG § 21-220; COMAR 10.19.03.02 and .07
Comments:
Per Peter Okojie. Pharmacy Manager, the pharmacist calls to verify original prescriptions sent via e-prescribing if needed.

2. PERSONNEL

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws Peter Okojie

Pharmacist Employees	License #	Exp Date
Peter Okojie	15719	10//2017
Olusegun Alani Anediran	16036	11/2016
Titiana Bangudi Attipoe	16087	1/2017
Olujimi Baratunde	20446	4/2017
Oluwaseun Ogunwuyi	19607	5/2017
Registered Technicians Shantrice Morris (On Duty)	Registration #	Exp Date 9/2016
Annderia F Simpson	T09888	2/2017
Diamond Jones	T14435	5/2017
Tymeka Conley	T03890	1/2017
Linnea Patterson	T07851	8/2017
Jasmine Jett	T11334	12/2017
Chloe Hogue	T11461	8/2016
Ricardo Watson	T08446	10/2016
Jnlicensed Personnel (non-registered) Mahamoud Aljack (On duty)	Title Pharmacy Intern	Duties fill, count
Ayoka Kenyatta (On duty)	Secretary	answer phones, paperwork

3. PERSONNEL TRAINING	Gr ⁱ
Yes ✓ No N/A	There are written policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed pharmacist. COMAR 10.34.21.03 and 10.34.21.05
Yes No N/A All personnel have received tra Yes No N/A Yes No N/A	All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03B(1) ining in: (check all that apply) COMAR 10.34.21.03B(3) and (4) Maintaining records Patient confidentiality Sanitation, hygiene, infection control Biohazard precautions Patient safety and medication errors COMAR 10.34.26.03
Comments: Reviewed training binder. Yes No The pharmacy was No The pharmacy was No No N/A 7	wholesale distributes to another pharmacy (COMAR 10.34.37) wholesale distributes to a wholesale distributor (COMAR 10.34.37) The wholesale distribution business exceeds 5% of the pharmacy annual sales COMAR 10.34.37)
Comments:	anger, the pharmacy does not wholesale distribute.
closed d	is designed to prevent unauthorized entry when the prescription area is uring any period that the rest of the establishment is open. (If yes, briefly
Comments:	how access is restricted.) COMAR 10.34.05.02A (5) the same time as the rest of the establishment.
	cy and/or pharmacy department has a security system. COMAR 5.02A (2)

Yes / No The permit holder shall prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services. COMAR 10.34.05.02A (3)
Comments:
Ok.
5. PHYSICAL REQUIREMENTS AND EQUIPMENT
Yes ✓ No Pharmacy area is clean and orderly. HO § 12-403(b) (11) (ii)2.
Yes / No The pharmacy provides a compounding service (non-sterile procedures).
Yes No If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice. COMAR 10.34.07.02
Yes No The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A
Yes ✓ No The pharmacy has hot an d cold running water.
Yes ✓ No The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01B
Yes No The medication refrigerator(s) have a thermometer and the current temperature is between (36-46F) USP. COMAR 10.34.07.01B
Temperature 40F, 41F
Yes No The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a)
Temperature 74F
Yes No N/A If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medications stored within it.
The pharmacy maintains at all times a current reference library that is appropriate to meet the needs of the practice specialty of that pharmacy and the consumers the pharmacy serves. HO § 12-403(b)(10) Yes No The pharmacy has online resources. HO § 12-403(b)(15)
Comments:
None.

6. PRESCRIPTION LABELING, FILES, AND STORAGE
Yes ✓ No Prescription files for each prescription prepared or dispensed are made and kept on file for at least 5 years. HO § 12-403(b)(13)(i)
The following label requirements are met if a drug is dispensed pursuant to a prescription: HO § 12-505
The name and address of the pharmacy; HG § 21-221(a)(1) The serial number of the prescription; HG § 21-221(a)(2) The date the prescription was filled; HO § 12-505(b)(1) and HG §21-221(a)(3) The name of the prescriber; HG § 21-221(a)(4) Yes No
Comments: None.
None.
7. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS
Yes No There are written policies that inform patients of the procedure to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care povider. COMAR 10.34.26.02
Yes ✓ No The pharmacy maintains a minimum of two (2) continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the
roles and responsibilities of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B
Yes ✓ No There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E
COMAR 10.34.26.03B Yes No There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E
COMAR 10.34.26.03B Yes No There is an ongoing quality assurance program that documents the competency and
COMAR 10.34.26.03B Yes ✓ No There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E Comments:

8. CONFIDENTIALTY
Yes No Confidentiality is maintained in the creation, storage, access disposal and disclosure of patient records. HO § 12-403(b)(13), COMAR 10.34.10.03A and HIPAA Regulations
Yes ✓ No Any identifiable information contained in a patient's record is not disclosed unless authorized by the patient, or an order of the court, or as authorized pursuant to HG §4-301 through §4-307. COMAR 10.34.10.03B
Comments:
Per Pharmacy Manager, the pharmacy requires valid ID to release patient's records.
9. INVENTORY CONTROL PROCEDURES
Yes No N/A The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR10.34.24.03
Yes No N/A The pharmacy has a procedure in place for removal of all expired drugs (both prescription and OTC). COMAR 10.34.12.01
Yes No N/A N/A The pharmacy maintains records of wholesale distribution to other pharmacies separately from its other records. COMAR 10.34.37.03
Yes No N/A The pharmacy maintains records of wholesale distribution to wholesale distributors separately from its records of wholesale distribution to other pharmacies. COMAR 10.34.37.03
Comments:
None.
10. CONTROLLED SUBSTANCES
Power of Attorney Peter Okojie
Yes ✓ No The pharmacy has a record of the most recent required biennial inventory of Schedule II-V controlled substances. COMAR 10.19.03.05B Inventory date: 12/3/2014
Biennial Inventory completed at Opening or Closing (circle one)
Yes No The inventories and records of Schedule II-V drugs are maintained and readily available. COMAR 10.19.03.05 and 21 CFR 1304.03
Yes No Records are kept of all receipts of controlled substances entered into the pharmacy inventory (including DEA Form 222 or CSOS orders). COMAR 10.19.03.05
Yes No There are written policies and records for return of CII, CIII-V.
Yes No Hard copy or electronic prescription files are maintained chronologically for 5 years.
Yes / No Schedule II controlled substances are dispersed throughout the stock of non-controlled
substances or stored in such a manner as to obstruct theft or diversion. COMAR 10.19.03.12B (2)

Yes ✓ No All contro	olled substances prescriptions bear the name and address of the prescriber and ent. COMAR 10.19.03.07D (1)
Yes / No The perm	it holder or pharmacist designee(s) has written policies and procedures for stigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B
Comments:	
Reviewed controlled return	ns to Guaranteed Returns & Cardinal Health.
11. AUTOMATED ME	EDICATION SYSTEMS Yes No (if No, go to #12)
Yes No N/A	The facility uses an automated device(s) as defined in COMAR 10.34.28.02.
Policies and proce	dures exist for (check all that apply): COMAR 10.34.28.04A
Yes No N/A	Operation of the system
Yes No N/A	Training of personnel using the system
Yes No N/A	Operations during system downtime
Yes No N/A	Control of access to the device
Yes No N/A	Accounting for medication added and removed from the system.
Yes No N/A	Sufficient safeguards are in place to ensure accurate replenishment of the automated medication system. If yes, describe safe guards. COMAR 10.34.28.06
Adequate records are main COMAR 10.34.28.1	ntained for at least two years addressing the following (check all that apply).
Yes No N/A	Maintenance records.
Yes No N/A	System failure reports.
Yes No N/A	weeks
Yes No N/A	=
Yes No N/A	Reports on system access and changes in access.
Yes No N/A	
Yes No N/A	Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, dosage forms, or drug entities, and minimize the potential for misidentification of medications, dosages, and dosage forms accessed from the automated medication system. COMAR 10.34.28.04B
Yes No N/A	The pharmacy has records, documents, or other evidence of a quality assurance program regarding the automated medication system in accordance with the requirements of COMAR 10.34.28
Comments:	

12. OUTSOURCING	Yes No ✓ (if No, go to #13)
Yes No N/A	The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02
Yes No N/A	The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02
Yes No N/A ✓	The facility serves as a secondary pharmacy. COMAR 10.34.04.02
Yes No N/A	The permit holder employs an outside agency/business entity for the provision of any pharmacy services, inclusive of staffing, remote order entry, and management.
	If yes: Name of agency, state of incorporation, service contracted, and State of Maryland License/Permit Number: COMAR 10.34.04.06E
Comments: N/A	
Yes No N/A	The permit holder has written policies and procedures to specify the duties that may be performed by outside personnel. COMAR 10.34.21.03B(3)
If the pharmacy outsource	s a prescription order:
Yes No N/A	The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D
Yes No N/A	Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06
Yes No N/A	Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists, and a record of the preparations made. COMAR 10.34.04.03 and .05
The pharmacist from the	e <u>primary</u> pharmacy documents the following in a readily retrievable and
Yes No N/A	IAR 10.34.04.06 (Check all that apply) That the prescription order was prepared by a secondary pharmacy.
Yes No N/A	The name of the secondary pharmacy.
Yes No N/A	The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
Yes No N/A	The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.
Yes No N/A	The date on which the prescription order was transmitted to the secondary pharmacy.
Yes No N/A	The date on which the medication was sent to the primary pharmacy.
Yes No N/A	The primary and secondary pharmacies are both licensed in the State of Maryland, or operated by the federal government. COMAR 10.34.04.06F
Yes No N/A	The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy. COMAR 10.34.04.06G

	secondary pharmacy maintains documentation in a readily retrievable and includes: COMAR 10.34.04.07 (Check all that apply)
Yes No N/A	That the prescription order was transmitted from another pharmacy.
Yes No N/A ✓	The name and information identifying the specific location of the primary pharmacy.
Yes No N/A	The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
Yes No N/A	The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
Yes No N/A	The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
Yes No N/A ✓	The date on which the prescription order was received at the secondary pharmacy.
Yes No N/A	The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.
13. Recommended Best I	Practices
Yes ✓ No A perp	netual inventory is maintained for Schedule II controlled substances.
Yes No There	are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
Yes ✓ No The pl	narmacy has written policies and procedures for the safe handling of drug recalls. See www.recalls.gov
Yes No The ph	narmacy maintains records of all recalls. See
INSPECTOR'S COMMI	ENTS:
check of CII perpetual inventiventory. Reviewed policies Mahamoud Aljack, on duty sent his application in to the pharmacy does not outsource internet or serve as a reposite	with Peter Okojie, Pharmacy Manger. There were no major discrepancies found during tory. There were no outdated or mis-labeled items pulled during check of pharmacy's and procedures found in a binder and training logs. There was 1 unlicensed intern filling and counting that was not found on the BOP website. Per Mr. Aljack, he has Board 3 approximately months ago. Per Peter Okojie, Pharmacy Manger, the e, wholesale distribute, repackage for another pharmacy, fill prescriptions via the cory or drop off site. Actions suggested per this inspection: 1) Send required paperwork a, Mahamoud Aljack to the Board attention Shanelle Young by 2/4/2016.
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***************************************	25
	66 10.404
Inspector Signature	Shandle gening
Pharmacist Name ((Pri	nt): Peter Okojie Date: 1/28/2016
Signature:	Lament & Wy aktion
Received a copy of this	
	Date and Pharmacist Signature

FINAL 09/02/2014

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

	#: N364630 ate Filled: 1/28/2016		
	NDC Number	ON HAND INVENTORY	PERPETU INVENTO
et 10/325mg	60951-0712-70	214	
norphone 4mg	00054-0264-25	1 1 6	613
norphone 8mg	42858-0303-01	150	1/\1
codone/IBU 7.5/200mg	53746-0145-01		
No major discrepancies.			-
No major discrepancies.			- - -
No major discrepancies.	SCHEDULE II AUDIT Drug N/A Date of last Inspection/Biennial N/A		-
Amount at last inspection/ Purchased since inspection Total inventory	Drug N/A Date of last Inspection/Biennial N/A biennial biennial biennial o	(A) (B) (C) = A + B	-
Amount at last inspection/ Purchased since inspection	Drug N/A Date of last Inspection/Biennial N/A biennial biennial 0 0	(B) (C) = A + B (D) (E) = C - D (F) (G) = (F-E) or (E-F)	
Amount at last inspection/ Purchased since inspection Total inventory Quantity dispensed Expected inventory Quantity on Hand	Drug N/A Date of last Inspection/Biennial N/A biennial biennial 0 0	(B) (C) = A + B (D) (E) = C - D (F)	e

PRESCRIPTION REVIEW

CII # N363984-N363558 DATE 1/12-1/16/2016

V# 363401-363499 E 1/11-1/11/2016	TS:
1/11-1/11/2016	ΓS:
	TOWN TO THE PARTY OF THE PARTY
2.	CARE ONE BUARANTA
	CARE ONE PHARMACY 2277 REISTERSTOWN AD BC9014816 BALTIMORE, MD 21217
	(410) 523-7500 Fex: (410) 523-7578 1 1-28-16 Dr. MAHLER
	Dr.Ph. (410) 821-7775
	T RV MOUTH EVERY 4 TO

OXYCODONE 30MG TAB #35

NDC# 00406-8530-01 MALLINCKRODT SPENSOEM BUSINESS OF THE PROPERTY OF T